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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-----------------------------|----------------------|-------------------------|------------------|
| 09/381,794 | 12/27/1999 | JAMES S. HUNTER | 454313-2540 | 4437 |
| 20999 7 | 7590 11/12/2002 | | | |
| FROMMER LAWRENCE & HAUG | | | EXAMINER | |
| NEW YORK, | /ENUE- 10TH FL. NY 10151 | | LEVY, NEIL S | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1616 | 1 (|
| | | | DATE MAILED: 11/12/2002 | 16 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary 07 3 | Applicant(s) Applicant(s) Applicant(s) |
|---|--|
| Exam | iner Group Arthrit |
| —The MAILING DATE of this communication appears on the | e cover sheet beneath the correspondence address— |
| Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIR OF THIS COMMUNICATION. | RE 30 MONTH(S) FROM THE MAILING DATE |
| Extensions of time may be available under the provisions of 37 CFR 1.136(a). Ir from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a reply within If NO period for reply is specified above, such period shall, by default, expire SII Failure to reply within the set or extended period for reply will, by statute, cause | the statutory minimum of thirty (30) days will be considered timely. X (6) MONTHS from the mailing date of this communication . |
| Status | - |
| Responsive to communication(s) filed on 7/23/0 | |
| ☐ This action is FINAL. | |
| Since this application is in condition for allowance except for formal accordance with the practice under Ex parte Quayle, 1935 C.D. 1 | |
| Disposition of Claims | , |
| Q-Claim(s) 22 - 4 (3) | is/are pending in the application. |
| Of the above claim(s) | is/are withdrawn from consideration |
| ☐ Claim(s) | is/are allowed. |
| | · |
| | |
| $\Box Claim(s) = 22 - 99$ $\Box Claim(s) = 22 - 99$ | is/are objected to. |
| J-Claim(s) 22 7 7 | are subject to restriction or election requirement. |
| Application Papers | |
| \square See the attached Notice of Draftsperson's Patent Drawing Review | v, PTO-948. |
| ☐ The proposed drawing correction, filed on is | • |
| ☐ The drawing(s) filed on is/are objected to by | the Examiner. |
| ☐ The specification is objected to by the Examiner. | |
| · | |
| ☐ The oath or declaration is objected to by the Examiner. | |
| ☐ The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 (a)-(d) | |
| □ The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 (a)-(d) □ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. ■ None of the CERTIFIED copies of the priorical received. □ received in Application No. (Series Code/Serial Number) | ity documents have been |
| □ The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 (a)-(d) □ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d) □ All □ Some* □ None of the CERTIFIED copies of the prioric received. □ received in Application No. (Series Code/Serial Number) □ received in this national stage application from the International | Il Bureau (PCT Rule 1 7.2(a)). |
| □ The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 (a)-(d) □ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. □ None of the CERTIFIED copies of the priority received. □ received. □ received in Application No. (Series Code/Serial Number) □ received in this national stage application from the International *Certified copies not received: | Il Bureau (PCT Rule 1 7.2(a)). |
| ☐ The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 (a)-(d) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the prioric received. ☐ received in Application No. (Series Code/Serial Number) | Il Bureau (PCT Rule 1 7.2(a)). |
| □ The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 (a)-(d) □ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § All □ Some* □ None of the CERTIFIED copies of the prioric □ received. □ received in Application No. (Series Code/Serial Number) □ received in this national stage application from the International *Certified copies not received: □ Attachment(s) □ Information Disclosure Statement(s), PTO-1449, Paper No(s). □ | Il Bureau (PCT Rule 1 7.2(a)). |
| ☐ The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 (a)-(d) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priorical received. ☐ received in Application No. (Series Code/Serial Number) | Il Bureau (PCT Rule 1 7.2(a)). |

U. S. Patent and Trademark Office PTO-326 (Rev. 9-97)

Part of Paper No. (6

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Receipt is acknowledged of CPA and Amendment, each of 7/23/02.

An abstract is still required.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 22-43, 48, 49, drawn to methods of treatment, classified in class
 514, subclass 407.
- Claims 44-49, drawn to methods of dual application, classified in class
 424, subclass 405.

The inventions are distinct, each from the other because:

The methods of Group I are independent and patentably distinct form those of Group II, as I does not require additional treatment and method II does not require formula II compounds of Group I; or optionally, formula I compounds of Group I, in order to provide treatment, as exemplified in Patent number 6395765, claim 28.

Because, the Groups have acquired a separate status in the art as shown by their different classification, and their recognized divergent subject matter, the search for any one group is not required for any other group. Furthermore because a search and examination of the entire application would place an undue burden on the Examiner, the present restriction requirement is proper for examination purposes.

This application contains claims directed to the following patentably distinct species of the claimed invention: species of formula I or II.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 22-49 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

None of the claims exclude formula II, or claim only a formula I compound.

This application contains claims directed to the following patentably distinct species of the claimed invention: the particular species of formula I; as required in the

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election of species of the rejection of 10/12/02, wherein the species, each, of R_1 through R_{13} and X is required to be identified.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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This application contains claims directed to the following patentably distinct species of the claimed invention: the species of the second agent, if group II is elected: the particular juvenile hormone or chitin synthesis inhibitor, as cited at Page 11 and 12 of the particular macrocyclic lactone as of claim 47.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 44-47 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

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the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant has selected Fipronil, in paper #10, and has not de-selected this species, nor changed the invention to the originally restricted out kit or composition inventions. However, the amendment clearly now provides for additional multiple inventive methods requiring combination treatment of multiple animal species, with attendant variation of efficacy, safety and health concerns associated with each drug applied to each animal species. The search required across all possible animal species and compounds now claimed would be a burdensome task for an examiner.

Because the above restriction/election requirement is complex, a telephone call to applicant's agent to request an oral election was not made. See M.P.E.P. Sec. 812.01.

An interview was requested, but was not able to be held. Examiner will set interview after invention and species to be examined have been identified.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is 308-2412. The examiner can normally be reached on Tuesday- Friday 7:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 305-4556 for regular communications and 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

Levy:mv October 28, 2002

> NEIL S. LEVY PRIMARY EXAMINER